UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,638	12/15/2003	Philippe Rouanet	029488-0113	9056

22428 7590 03/13/2007

FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
COTTON, ABIGAIL MANDA	
ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/734,638	ROUANET ET AL.	
	Examiner	Art Unit	
	Abigail M. Cotton	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2007 and 22 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-28,31-36 and 38-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-28, 31-36 and 38-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 3, 2007, has been entered.

Claims 26-28, 31-36 and 38-48 are pending in the application and are being examined on the merits herein.

The Examiner acknowledges Applicants submission of the application data sheet on January 3, 2007 listing the inventors' residence and post office address.

Applicant's arguments regarding the rejections of the claims over the prior art have been considered but are moot in view of the new grounds of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 26-28, 31-34, 36, 39-45 and 47 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 4,919,937 to Mauvais-Jarvis et al, in view of DE 3836862 A1 to Gunther et al, published May 3, 1990.

Mauvais-Jarvis et al. teaches a percutaneously administrable drug of the hydroalcoholic type comprising 4-hydroxytamoxifen, and which can also comprise the steroid hormone progesterone (see abstract, column 2, lines 25-35 and column 3, lines 30-45, in particular.) Mauvais-Jarvis et al. further exemplifies a composition comprising progesterone, 4-hydroxytamoxifen, ethyl alcohol and water (see column 3, lines 30-45, in particular.) Mauvais-Jarvis et al. further teaches that the hydroalcoholic gel comprises various excipients required for enabling percutaneous penetration to take place (see column 3, lines 10-40, in particular.)

Regarding claim 26, it is noted that, for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, the transitional phrase "consisting essentially of" is being construed as equivalent to "comprising," absent a clear indication in the specification or claims of what is meant by, i.e. what is being excluded from the composition by, the phrase "consisting essentially of." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355, and MPEP 2111.03.

Regarding claim 39, it is noted that as Mauvais-Jarvis et al. teaches that the composition can contain the active agent that is 4-hydroxytamoxifen, it is considered that the reference teaches providing a composition in which 4-hydroxytamoxifen is the sole pharmaceutically active agent. Also, the composition containing 4-hydroxytamoxifen and progesterone of Mauvais-Jarvis et al. is considered to meet the limitation of being a composition "comprising a pharmaceutically active agent ... wherein the pharmaceutically active agent consists of 4-hydroxy tamoxifen" (underline added, i.e. a composition that has at least one pharmaceutically active agent that is 4-hydroxy tamoxifen) as recited in claim, because the composition contains an active agent that is 4-hydroxy tamoxifen.

It is furthermore noted that Mauvais-Jarvis et al. teaches that the percutaneous administration composition and method arose out of studies with percutaneous administration of hormonal steroids such as progesterone (see column 1, lines 56-column 2, line 25, in particular), and thus teaches that the methods and vehicles suitable for percutaneous administration of hormonal steroids can also be used for the percutaneous administration of the 4-hydroxytamoxifen.

Mauvais-Jarvis et al. does not specifically teach that the composition comprises a fatty acid ester penetration enhancer, as recited in claims 26 and 39, such as isopropyl myristate, as recited in claims 31 and 42.

Gunther et al. teaches a composition for transdermal administration of steroid hormones comprising a fatty acid ester (see abstract, in particular), as recited in claim 26. Gunther et al. teaches that fatty acid esters ensure adequate penetration of the active ingredient through the skin for therapy, and that a preferred fatty acid ester is isopropyl myristate (see specification, first page, in particular), as recited in claim 31.

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the isopropyl myristate of Gunther et al. in the percutaneous composition of Mauvais-Jarvis et al, because Mauvais-Jarvis et al. teaches that the composition comprising the 4-hydroxy tamoxifen and progesterone steroid composition comprises ingredients to enable percutaneous penetration, and Gunther et al. teaches that the isopropyl myristate ensures percutaneous administration of steroids. Thus, one of ordinary skill in the art would have been motivated to combine the isopropyl myristate into the composition of Mauvais-Jarvis et al, with the expectation of providing a percutaneous formulation that provides suitable penetration of the 4-hydroxy tamoxifen and progesterone composition.

It would furthermore have been obvious to one of ordinary skill in the art at the time the invention was made to provide the isopropyl myristate of Gunther et al. in the percutaneous composition of Mauvais-Jarvis et al, because Mauvais-Jarvis et al. teaches that vehicles suitable for the percutaneous administration of steroidal hormones

can also be used for the percutaneous administration of 4-hydroxytamoxifen, whereas Gunther et al. teaches that the isopropyl myristate ensures percutaneous administration of steroids. Thus, one of ordinary skill in the art would have been motivated to combine the isopropyl myristate into the composition of Mauvais-Jarvis et al, with the expectation of providing a percutaneous formulation that provides suitable penetration of the 4-hydroxy tamoxifen.

Accordingly, claims 26 and 29 are obvious over the teachings of Mauvais-Jarvis et al. in view of Gunther et al.

Regarding claims 27 and 40, Mauvais-Jarvis et al. teaches the hydroalcoholic gel as recited in the claim (see column 3, lines 29-55, in particular.)

Regarding claims 28 and 41, the Mauvais-Jarvis et al. exemplifies a composition comprising a hydroalcoholic composition comprising the 4-hydroxytamoxifen, an aqueous vehicle (water), an alcoholic vehicle (ethyl alcohol), and a gelling agent (Carbopol 934) (see column 3, lines 30-40, in particular), whereas Gunther et al. teaches providing the penetration enhancer, as discussed above. Accordingly, the combined teachings Mauvais-Jarvis et al. and Gunther et al render the claimed composition obvious.

Regarding claims 31 and 42, Mauvais-Jarvis et al. exemplifies a composition comprising 0.15 g (0.15%) of 4-hydroxy tamoxifen, 50 mL of 95% ethyl alcohol, a quantity of water, and 1 g (1%) of carbopol 934 (gelling agent) (see column 3, lines 30-40, in particular), and thus teaches a composition having amounts of ingredients (a) and (c)-(e) that are close to and/or overlap with the ranges recited in the claim. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the components provided in the hydroalcoholic gel composition, according to the guidance provided by Mauvais-Jarvis et al, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.) Regarding the amount of the isopropyl myristate provided, as recited in part (e) of claims 31 and 42, as well as claims 33 and 44, it is noted that Gunther et al. exemplifies compositions with 10% and 2% isopropyl myristate. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the isopropyl myristate provided in the composition, according to the guidance provided by Mauvais-Jarvis et al. and Gunther et al, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claims 32 and 43, it is noted that Mauvais-Jarvis et al. exemplifies a composition comprising 4-hydroxy tamoxifen in an amount of 0.15g (0.15%), which is considered to meet the limitation of being "about" 0.5% by weight, as recited in the claim (see column 3, lines 10-40, in particular.) Gunther teaches that concentration of active ingredient of from 0.2 to 20 weight percent can be provided by utilizing the fatty acid ester penetration enhancers (see first page, in particular.) Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of 4-hydroxy tamoxifen provided in the composition, according to the guidance provided by Mauvais-Jarvis and the penetration enhancement teachings of Gunther, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claims 34 and 45, Mauvais-Jarvis et al. exemplifies the composition comprising 95% ethyl alcohol in an amount of 50 ml (see column 3, lines 10-40, in particular), which is close to and/or overlaps with the amount as claimed. Regarding claims 36 and 47, Mauvais-Jarvis et al. teaches the composition having Carbopol 934 (gelling agent), a polyacrylic acid, in an amount of 1.5 g (1.5%) (see column 3, lines 10-40, in particular), which meets the limitation of the claim. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found

it obvious to vary and/or optimize the amount of ethyl alcohol and/or gelling agent provided in the composition, according to the guidance provided by Mauvais-Jarvis et al. and Gunther et al, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Claims 26-28, 31-34, 36, 39-45 and 47 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 4,919,937 to Mauvais-Jarvis et al, in view of EP 0 513 832 to Prakash Parab, published November 19, 1992.

Mauvais-Jarvis et al. teaches a percutaneously administrable drug of the hydroalcoholic type comprising 4-hydroxytamoxifen, and which can also comprise the steroid hormone progesterone (see abstract, column 2, lines 25-35 and column 3, lines 30-45, in particular.) Mauvais-Jarvis et al. further exemplifies a composition comprising progesterone, 4-hydroxytamoxifen, ethyl alcohol and water (see column 3, lines 30-45, in particular.) Mauvais-Jarvis et al. further teaches that the hydroalcoholic gel comprises various excipients required for enabling percutaneous penetration to take place (see column 3, lines 10-40, in particular.)

Regarding claim 26, it is noted that, for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, the transitional phrase “consisting

essentially of" is being construed as equivalent to "comprising," absent a clear indication in the specification or claims of what is meant by, i.e. what is being excluded from the composition by, the phrase "consisting essentially of." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355, and MPEP 2111.03.

Regarding claim 39, it is noted that as Mauvais-Jarvis et al. teaches that the composition can contain the active agent that is 4-hydroxytamoxifen, it is considered that the reference teaches providing a composition in which 4-hydroxytamoxifen is the sole pharmaceutically active agent. Also, the composition containing 4-hydroxytamoxifen and progesterone of Mauvais-Jarvis et al. is considered to meet the limitation of being a composition "comprising a pharmaceutically active agent ... wherein the pharmaceutically active agent consists of 4-hydroxy tamoxifen" (underline added, i.e. a composition that has at least one pharmaceutically active agent that is 4-hydroxy tamoxifen) as recited in claim, because the composition contains an active agent that is 4-hydroxy tamoxifen.

Mauvais-Jarvis et al. does not specifically teach that the composition comprises a fatty acid ester penetration enhancer, as recited in claims 26 and 39, such as isopropyl myristate, as recited in claims 31 and 42.

Parab teaches enhancing the dermal or transdermal penetration of topically applied pharmacologically active agents (see abstract, in particular.) Parab teaches

that isopropyl myristate is known as a penetration enhancer for topical preparations (see page 2, lines 57-58, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the isopropyl myristate of Parab in the percutaneous composition of Mauvais-Jarvis et al, because Mauvais-Jarvis et al. teaches that the composition comprising the 4-hydroxy tamoxifen comprises ingredients to enable percutaneous penetration, and Parab et al. teaches that the isopropyl myristate is a known penetration enhancer that can be used in compositions intended enhance the penetration of pharmacological active agents. Thus, one of ordinary skill in the art would have been motivated to combine the isopropyl myristate into the composition of Mauvais-Jarvis et al, with the expectation of providing a percutaneous formulation that provides suitable penetration of the 4-hydroxy tamoxifen.

Accordingly, claims 26 and 29 are obvious over the teachings of Mauvais-Jarvis et al. in view of Parab.

Regarding claims 27 and 40, Mauvais-Jarvis et al. teaches the hydroalcoholic gel as recited in the claim (see column 3, lines 29-55, in particular.)

Regarding claims 28 and 41, the Mauvais-Jarvis et al. exemplifies a composition comprising a hydroalcoholic composition comprising the 4-hydroxytamoxifen, an

aqueous vehicle (water), an alcoholic vehicle (ethyl alcohol), and a gelling agent (Carbopol 934) (see column 3, lines 30-40, in particular), whereas Parab. teaches providing the penetration enhancer, as discussed above. Accordingly, the combined teachings Mauvais-Jarvis et al. and Parab render the claimed composition obvious.

Regarding claims 31 and 42, Mauvais-Jarvis et al. exemplifies a composition comprising 0.15 g (0.15%) of 4-hydroxy tamoxifen, 50 mL of 95% ethyl alcohol, a quantity of water, and 1 g (1%) of carbopol 934 (gelling agent) (see column 3, lines 30-40, in particular), and thus teaches a composition having amounts of ingredients (a) and (c)-(e) that are close to and/or overlap with the ranges recited in the claim. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the components provided in the hydroalcoholic gel composition, according to the guidance provided by Mauvais-Jarvis et al, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.) Regarding the amount of the isopropyl myristate provided, as recited in part (e) of claims 31 and 42, as well as claims 33 and 44, it is noted that Parab teaches that isopropyl myristate (IPM) can be incorporated in an amount of from 1 wt% to abut 30 wt% (see page 4, lines 35-45, in particular.) Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the

amount of the isopropyl myristate provided in the composition, according to the guidance provided by Mauvais-Jarvis et al. and Parab, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claims 32 and 43, it is noted that Mauvais-Jarvis et al. exemplifies a composition comprising 4-hydroxy tamoxifen in an amount of 0.15g (0.15%), which is considered to meet the limitation of being "about" 0.5% by weight, as recited in the claim (see column 3, lines 10-40, in particular.) Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of 4-hydroxy tamoxifen provided in the composition, according to the guidance provided by Mauvais-Jarvis and the penetration enhancement teachings of Parab, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claims 34 and 45, Mauvais-Jarvis et al. exemplifies the composition comprising 95% ethyl alcohol in an amount of 50 ml (see column 3, lines 10-40, in particular), which is close to and/or overlaps with the amount as claimed. Regarding

claims 36 and 47, Mauvais-Jarvis et al. teaches the composition having Carbopol 934 (gelling agent), a polyacrylic acid, in an amount of 1.5 g (1.5%) (see column 3, lines 10-40, in particular), which meets the limitation of the claim. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of ethyl alcohol and/or gelling agent provided in the composition, according to the guidance provided by Mauvais-Jarvis et al. and Parab, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Claims 35 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over either (i) U.S. Patent No. 4,919,937 to Mauvais-Jarvis et al, issued April 24, 1990, in view of DE 3836862 A1 to Gunther et al, published May 3, 1990, as applied to claims 26-28, 31-34, 36, 39-45 and 47 above, or (ii) U.S. Patent No. 4,919,937 to Mauvais-Jarvis et al, in view of EP 0 513 832 to Prakash Parab, published November 19, 1992, as applied to claims 6-28, 31-34, 36, 39-45 and 47 above, and further in view of U.S. Patent No. 5,720,963 to Walter P. Smith, issued February 24, 1998.

Mauvais-Jarvis et al. and Gunther et al or Parab, are applied as discussed for claims 26-28, 31-34, 36, 39-45 and 47 above, and teach a hydroalcoholic gel

composition for percutaneous administration comprising and active agent that "consists" or "consists essentially" of 4-hydroxy tamoxifen.

Mauvais-Jarvis et al. also exemplify a composition comprising an aqueous vehicle in an amount that is close to and/or overlaps with that recited in claims 35 and 46. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the aqueous vehicle provided in the composition, according to the guidance provided by Mauvais et al. and Gunther et al or Parab, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

The references do not specifically teach providing an aqueous vehicle that is a phosphate buffered solution, as recited in claims 35 and 46.

Smith teaches topically applied treatments for skin, which can comprise gels (see abstract, in particular.) Smith teaches that topical treatments can be pH adjusted to within a desired range and may be buffered with buffers such as trimethylolaminomethan (tromethane) or phosphate buffer (see column 32, lines 20-30, in particular), as recited in claims 35 and 46.

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the buffers of Smith in the hydroalcoholic gel of Mauvais-Jarvis et al. and Gunther et al or Mauvais-Jarvis et al. and Parab, because Mauvais-Jarvis and Gunther et al. or Mauvais-Jarvis et al. and Parab teach the composition is applied percutaneously (topically), and Smith teaches the buffers can be provided to maintain a desired pH of the a topical composition. Thus, one of ordinary skill in the art would have been motivated to provide the buffers of Smith in the composition of Mauvais-Jarvis et al. and Gunther et al. or Mauvais-Jarvis et al. and Parab, with the expectation of maintaining suitable pH of the composition for topical application.

Claims 38 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over either (i) U.S. Patent No. 4,919,937 to Mauvais-Jarvis et al, issued April 24, 1990, in view of DE 3836862 A1 to Gunther et al, published May 3, 1990, as applied to claims 26-28, 31-34, 36, 39-45 and 47 above, or (ii) U.S. Patent No. 4,919,937 to Mauvais-Jarvis et al, in view of EP 0 513 832 to Prakash Parab, published November 19, 1992, as applied to claims 6-28, 31-34, 36, 39-45 and 47 above, and further in view of further in view of U.S. Patent No. 6,013,270 to Hargraves et al, issued January 11, 2000.

Mauvais-Jarvis et al. and Gunther et al. or Parab, are applied as discussed for claims 26-28, 31-34 and 36 above, and teach a hydroalcoholic gel composition for

percutaneous administration comprising and active agent that "consists" or "consists essentially" of 4-hydroxy tamoxifen.

The references do not specifically teach that the composition is packaged in a unit dose packet of a multiple dose container with a metered pump, as recited in claim 38.

Hargraves et al. teaches a skin care kit having a skin care composition contained within a dispenser (see abstract, in particular.) Hargraves et al. teaches that the dispenser can comprise a metered pump that an provide multiple doses and is suitable for dispensing skin care compositions such as for medical applications and body care applications (see column 14, line 45 through column 20, line 15, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the dispenser of Hargraves et al. to dispense the composition of Mauvais-Jarvis et al. and Gunther et al. or Mauvais-Jarvis et al. and Parab, because Mauvais et al. and Gunther et al. or Mauvais-Jarvis et al. and Parab teach a medical composition for percutaneous application (topical application), and Hargraves et al. teaches the dispenser dispenses topical compositions, such as medical compositions. Thus, one of ordinary skill in the art would have been motivated to provide the dispenser for the composition of Mauvais-et al. and Gunther et al. or

Mauvais-Jarvis et al. and Parab, with the expectation of providing a device suitable for the dispensing of the topical composition.

Response to Arguments

Applicant's arguments with respect to the rejections of the claims have been considered but are moot in view of the new grounds of rejection.

Conclusion

No claims are allowed.

The prior art made of record and not relied upon that is considered pertinent to applicant's disclosure is listed in the attached PTO-892 form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER